

### **REMARKS**

Claims 1-5, 7, 8 and 10 were pending in the instant application. By this amendment, Claims 1 and 2 have been amended, Claims 11 and 12 have been added, and Claim 10 has been canceled, without prejudice to the Applicants' right to pursue the canceled claims in this or other applications.

In particular, Claim 1 has been amended to replace "treatment or protection against a neuromuscular or muscular condition of heart tissue" with "treating or protecting against injury or damage to heart tissue in mammals." In view of the amendment to Claim 1 deleting "neuromuscular or muscular condition," Claim 2 has been amended to replace "condition" with "injury or damage." Support for the amendments is found at page 5, lines 4-9 and 18-20; page 7, lines 26-30; page 14, lines 19-20; and page 34, lines 1-5. Claims 11 and 12 have been added to claim certain embodiments of the invention related to mammals having specific heart conditions. Support for new Claims 11 and 12 is found at page 5, line 28 and page 14, lines 19-20. As such, no new matter has been added.

Therefore, Claims 1-5, 7, 8, 11, and 12 will be pending upon entry of the instant amendment.

### **THE REJECTIONS UNDER 35 U.S.C. § 112, FIRST PARAGRAPH, FOR LACK OF ENABLEMENT SHOULD BE WITHDRAWN**

Claims 1, 3-5, 7, 8, and 10 have been rejected under 35 U.S.C. § 112, first paragraph, as the specification is allegedly not enabling for a method for treatment or protection against a neuromuscular or muscular condition of a heart tissue. The Examiner indicated that the specification was enabling for "a method for the treatment of ischemic heart injury or protection against ischemic heart injury comprising administering peripherally to a mammal in need of said treatment, a non-toxic amount of EPO effective for the treatment of ischemic heart injury or protection against ischemic heart injury," in the first paragraph of

page 9 of the Office Action dated April 9, 2003. The Examiner also indicated that “EPO may treat or offer some protection against the necrosis or myocardial infarction (tissue damage of the heart) caused by coronary artery occlusion,” in the paragraph abridging pages 4 and 5 of the Office Action dated April 20, 2004. Thus, the subject matter that the Examiner indicated as enabled by the specification corresponds to a method for treating or protecting against injury or damage to heart tissue in mammals.

In view of the Examiner’s concerns, Claim 1 has been amended to recite “treating or protecting against injury or damage to heart tissue in mammals.” Applicants submit that Claim 1, as amended, and claims dependent thereon, *i.e.*, Claims 3-5, 7 and 8, are enabled in view of the disclosure of the specification and the working examples presented therein (see page 14, lines 19-20; example 6 at page 34, lines 1-20; and Figures 6A and 6B). Thus, undue experimentation would not be required by one skilled in the art to practice the methods of the invention and administer EPO to successfully treat or protect against damage or injury to heart tissue.

In view of the foregoing reasoning and amendment, Applicants submit that the rejection for lack of enablement under 35 U.S.C. §112, first paragraph, should be withdrawn.

### **CLAIM OBJECTIONS**

Claim 2 has been objected to for depending from a rejected claim. In view of the amendment to Claim 1, Applicants submit that the objection has been overcome and respectfully request withdrawal of the objection.

### CONCLUSION

Applicants respectfully request entry and consideration of the foregoing amendments and remarks. No new matter has been introduced. The claims are believed to be free of the art and patentable. Withdrawal of all of the rejections and an early allowance is earnestly sought.

Respectfully submitted,

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